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TITLE: **Impact of Institutional - and Individual – Level Discrimination on Medical Care & Quality of Life among Breast Cancer Survivors**

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14. ABSTRACT
During this reporting period, we completed qualitative one-on-one and focus group interviews with breast cancer survivors from 7 racial/ethnic groups (see Appendix A), continued rigorous analysis of the qualitative data, systematizing the data such that specific themes were identified, conducted an exhaustive assessment of existing literature and instruments for survey development, combined results of the qualitative analysis and literature review, and successfully developed a comprehensive quantitative survey for cognitive testing. This instrument incorporates relevant items from existing tools as well as *de-novo* questions aimed to address novel themes identified in the qualitative data. We reviewed each survey question for potential problems and developed specific cognitive questions to test for these problems accordingly. We conducted extensive training on the cognitive instrument and are in the process of translating the survey and cognitive instrument into Spanish, Chinese and Tagalog. We have completed 2 initial drafts of manuscripts to report the qualitative findings and we have plans for a third manuscript based on the instrument development process.

15. SUBJECT TERMS
Qualitative analysis, focus group, cognitive interview, instrument development

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INTRODUCTION

The objective of this study is to measure the prevalence and impacts of discrimination at the institutional- and individual- level to identify the underlying factors contributing to disparities in breast cancer diagnosis, treatment, and quality of life. The specific aims are to: 1) develop a survey tool tailored towards cancer patients for assessing discrimination in health care settings; 2) quantify the prevalence of individual- and contextual-level discrimination across racial/ethnic groups; and 3) assess the effects of individual- and contextual-level discrimination on disparities in: a) late stage diagnosis, b) cancer treatment (including breast conserving surgery (BCS) and adjuvant radiation), and c) quality of life (QOL). This study comprises two components: developmental (Aim 1) and application (Aims 2-3). The developmental component uses qualitative research to develop an instrument tailored for breast cancer patients. Because tools have not been developed for cancer patients nor for different races/ethnicities, we will conduct focus groups and qualitative (one-on-one) interviews to discern relevant discrimination topics. The topics, together with existing instruments, will be used to develop an instrument to be cognitive-tested in a small sample of patients. We will then conduct a pilot test, including a reliability test-retest, of the instrument and field methodology to optimize its reliability. In the application component, we will conduct a cross-sectional epidemiologic study using a multilevel approach by incorporating individual- and neighborhood-level information including: 1) previously collected geographic information systems (GIS) data about the social and built environment; and 2) telephone interviews (~14 months after diagnosis) with a population-based cohort of breast cancer patients.

BODY

The original Statement of Work for the first three years of the study is as follows:

Task 1   Obtain IRB approvals, design and obtain approvals on focus group and qualitative interview instruments, translate and back-translate instruments, develop study tracking system and training materials, Months 1-6
    a.   Prepare and submit IRB applications for DOD and NCCC.
    b.   Apply for cancer registry data from the Greater Bay Area Cancer Registry (GBACR).
    c.   Develop MS Access tracking system.
    d.   Develop interviewer training manual.
    e.   Translate, back-translate, convene meeting(s) to decenter instruments.
    f.   Hire staff.
    g.   Obtain first case listing data from the GBACR, download into tracking system.
    g.   Organize community advisory committee meeting to introduce study and obtain feedback about general research strategy.
    Deliverables: IRB approvals, finalized instruments for focus group and qualitative interviews, community advisory committee feedback

Task 2   Conduct focus group and qualitative interviews, Months 7-12
    a.   Select breast cancer patients for contacting regarding focus group and qualitative interviews.
    b.   Recruit breast cancer patients for fulfilling the numbers of required focus group and qualitative participants for each racial/ethnic group.
    c.   Conduct focus group and qualitative interviews.
    d.   Transcribe interviews.
    Deliverables: completed focus group and qualitative interviews, transcripts of completed interviews

Task 3   Conduct qualitative data analysis, design epidemiologic survey instrument, Months 13-18
    a.   Code the transcribed interviews.
    b.   Conduct thematic-driven qualitative data analysis.
    c.   Design epidemiologic survey instrument.
    d.   Translate epidemiologic survey instrument.
    e.   Develop and obtain IRB approval for recruitment materials and procedures for cognitive interviews.
    Deliverables: completed qualitative data analysis, epidemiologic survey instrument and recruitment materials for cognitive interviews

Task 4   Conduct cognitive interviews, revise epidemiologic survey instrument as necessary, Months 19-21
      a. Select breast cancer patients for contacting regarding cognitive interviews.
      b. Recruit breast cancer patients for fulfilling the numbers of required cognitive interviews for each racial/ethnic group.
      c. Conduct cognitive interviews.
      d. Convene study staff meetings to discuss results from cognitive interviews and to revise instrument as necessary.
    Deliverables: completed cognitive interviews, refined epidemiologic survey instrument based on cognitive testing

Task 5   Conduct pilot testing, revise epidemiologic survey instrument as necessary, Months 22-24
      a. Select breast cancer patients for contacting regarding pilot test interviews.
      b. Recruit breast cancer patients for fulfilling the numbers of required pilot test interviews for each racial/ethnic group.
      c. Conduct pilot test interviews.
      d. Conduct reliability test-retest interview.
      e. Conduct data analysis.
      f. Convene study staff meeting to discuss results from pilot test interviews and to revise instrument as necessary.
      g. Convene community advisory committee to review study instrument and field recruitment methods and obtain advice regarding appropriateness, relevance, and feasibility.
    Deliverables: completed pilot test interviews, refined epidemiologic survey instrument and field methods based on pilot testing, community advisory committee feedback

Task 6   Conduct epidemiologic interviews, GIS analysis to create neighborhood variables, Months 25-40
      a. Select breast cancer patients for contacting regarding epidemiologic interviews.
      b. Recruit breast cancer patients for the epidemiologic interviews.
      c. Conduct epidemiologic interviews.
      d. Design data entry system in MS Access.
      e. Edit questionnaire, conduct double data entry.
      f. Conduct quarterly, interim data analysis to look for unusual data patterns.
      g. Clean and prepare epidemiologic interview data for analysis.
      h. Conduct GIS analysis to create study-specific neighborhood measures and merge to interview dataset.
      i. Create statistical program to conduct multilevel modeling analysis.
      j. Conduct test-runs of multilevel modeling analysis.
    Deliverables: completed epidemiologic interviews, epidemiologic analytic dataset, multilevel modeling analysis program

Progress

The last annual report was submitted in December 2009. This current report includes progress from July 2009 – July 2010, so some content may overlap. To date, we have completed tasks 1 through 3 outlined in the Statement of Work. As mentioned in our previous annual report (submitted in December 2009), we had some set-backs in the study progress due to staffing issues, maternity leave, and the qualitative phase taking longer than expected in general. In addition, IRB approvals, both initially and for continuing reviews and modifications, have taken longer than expected due to State of California furloughing. As mentioned in the report of December 2009, analysis, transcription, and translation of the qualitative data was time consuming. Our initial look at the qualitative data indicated to us that simply adapting existing discrimination survey items, particularly in the medical, or health care, setting, would be inadequate given that breast cancer patients did not explicitly identify discrimination. Yet, very subtle forms of medical discrimination were evident from the qualitative data; however, this meant that we needed to devote more effort than initially expected to identifying these discrimination-related themes to inform the development of the survey items. We successfully classified the coding of five reviewers for 31 qualitative interviews (24 one-on-one and 7 focus group interviews) into a

matrix system which allowed us to systematically look at the data and identify several novel emergent themes. We completed the thematic analysis in early spring 2010. We did not initially expect to publish on the qualitative data, but the themes are interesting and novel, warranting publication. We have completed 2 drafts of manuscripts summarizing the qualitative results and we expect these will be submitted for publication in the fall/winter of 2010. In addition, we have engaged with a colleague from UCSF to work on a third manuscript based on the qualitative findings.

In terms of the questionnaire development process **(see Figure 1)**, much of the analysis of the focus group and one-on-one qualitative interviews focused on identifying relevant health care discrimination topics. We have identified several emergent themes that we would like to capture in the epidemiologic questionnaire. Our exhaustive review of the existing literature and tools, in addition to conversations with colleagues who are also developing or have developed discrimination measures, has shown us that <u>there currently exist very few questions that would be appropriate for adapting to our study population</u>. The vast majority of the literature has focused on general discrimination in everyday settings; few studies have focused on discrimination in the health care setting; and, of most relevance to us, <u>no studies of discrimination, to our knowledge, have been conducted among breast cancer patients</u>. Furthermore, because we found that patients are generally unable or unwilling to identify discrimination, or unequal care, when it exists, because of various factors specific to the region as well as the population, this requires much more detailed questions specific to various aspects of the health care encounter to discern discriminatory practices.

Figure 1. Overview of the questionnaire development process
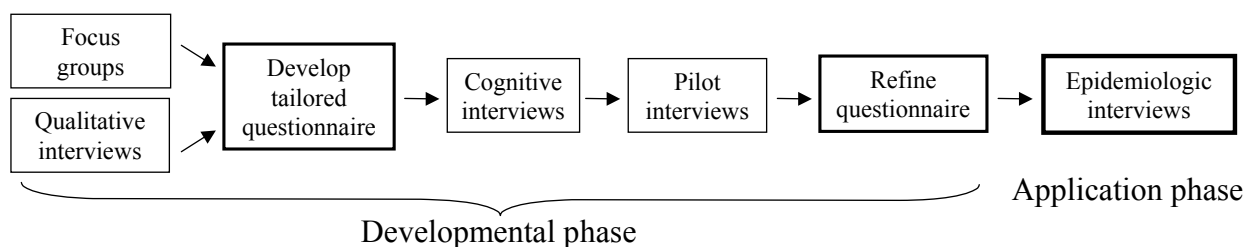
Over the course of several months, we met with members of the research team to prioritize, adapt, and develop new questions. We used the <u>most prominent themes identified from our qualitative research</u> to inform the development of new questions, in addition to using some existing tools. We obtained input from bilingual and bicultural staff interviewers to address the cultural appropriateness and ease of administering the questions. In March 2010, we sent a selected list of the most problematic questions from the questionnaire to our Community Advisory Committee and study consultants. Based on their feedback, we further refined the draft questionnaire and used this as the basis for developing a cognitive instrument to test the questions. The next phase of questionnaire development will be to conduct cognitive interviews, which are expected to occur from August through October of this year among several different racial/ethnic groups. The cognitive instrument was designed to test various forms of key questions covering the same domain to help determine the most accurate and effective questions to keep in the final questionnaire. In addition, each survey question was analyzed to assess potential problems in administration and comprehension, and cognitive questions regarding these issues were designed accordingly. The cognitive instrument is currently being translated into several languages, including Spanish, Chinese, and Tagalog. Electronic tools for documenting the results of the cognitive testing and the evolution of the survey questions was developed to track reasons why draft items were modified or discarded during the questionnaire development process.

In addition to the primary domain of interest (discrimination), we also identified several other domains of interest to include in the questionnaire: stress, coping, social support and social networks, social burden, patient-provider communication, cultural factors and beliefs, cultural health capital, sociodemographics, treatment and comorbidity, quality of life, neighborhood environment, clinical trial participation, immigrant and children-of-immigrants stress, and social desirability bias. Questions for these domains were adapted from existing tools after consultation with experts within each domain. The concept of cultural health capital, defined

as the repertoire of cultural skills, verbal and nonverbal competencies, attitudes and behaviors, and interactional styles, cultivated by patients and clinicians alike, that, when deployed, may result in more optimal health care relationships, is a new concept that has not been explored empirically, but one which we found relevant based on our qualitative data analysis. We have established collaboration with Dr. Janet Shim (UCSF) to conduct secondary analysis of the deidentified qualitative data to specifically identify issues of cultural health capital.

Since we are rigorously testing the tools that we are developing, we will also be documenting the process and reporting our results in a separate process manuscript. We believe that these research questions that are currently being developed will have broad application to a number of different disease outcomes.

At this time, we have received IRB approval of the cognitive and epidemiologic phase instruments and we expect to make modifications to the instruments and forms as needed, pending results from cognitive interviews, and to receive IRB approval for these modifications as expedited review in November, 2010. We have also received IRB approval for the secondary qualitative data analysis with Dr. Shim. To make up for the study delays, we plan to increase our interviewers' levels of effort during the epidemiologic phase and we expect that we will be able to complete the epidemiologic interviews in a considerably shorter amount of time than originally outlined in the Statement of Work. In addition, we have already begun to assemble the institutional and contextual data, which are tasks outlined in Task 6 of the Statement of Work. We expect to conduct preliminary analyses of the epidemiologic data as they are being collected.

KEY RESEARCH ACCOMPLISHMENTS

- Successfully conducted 31 qualitative one-on-one and focus group interviews with breast cancer survivors from 7 racial/ethnic groups.
- Undertook rigorous qualitative data analysis, systemizing data into a matrix of emergent themes and identifying several novel themes.
- Conducted comprehensive review of existing tools for constructs of interest.
- Developed novel survey questions based on qualitative themes.
- Developed survey instrument incorporating existing tools and novel questions.
- Obtained interviewer, Community Advisory Committee and study consultant input on survey instrument.
- Developed cognitive instrument for testing epidemiologic survey instrument.
- Developed electronic system for documenting results of cognitive survey and evolution of question development.
- Process has lead to drafts for 2 novel manuscripts and potential for a third.
- Established collaboration with UCSF research scientist for secondary qualitative data analysis.

REPORTABLE OUTCOMES

- While previous research has focused on the positive aspects of social support and breast cancer, preliminary findings from the qualitative phase of our study suggest that breast cancer survivors, in particular racial/ethnic minorities, may experience more negative aspects of social support than previously thought. While non-Hispanic white women generally reported being satisfied with their familial support and extended network support (i.e. support groups, spiritual communities), women from ethnic minority groups either had smaller support networks or experienced shifts in the dynamics of their interpersonal relationships, including more marital issues and more negative social interactions with family, friends and co-workers. Women also reported feeling burdened by the need to help families and friends cope with the illness and were compelled to hide treatment side effects to avoid causing worry or becoming a burden to their families, suggesting some cultural influences. This increased need to give support to others while not receiving adequate support for themselves during the process of diagnosis and treatment can increase social strain and stress, leading to poorer quality of life for survivors.
- Our qualitative analysis of perceptions of discrimination in the medical setting suggests that discrimination is prevalent and that breast cancer survivors experienced discrimination in both the

general and medical setting. Despite repeated assertions by participants that they live in a racially-diverse geographic area where there should not be discrimination, findings from our qualitative analysis suggest that discrimination is still prevalent in different settings and in multiple forms with varying degrees of acknowledgement from perpetrators and victims.   The predominant forms of discrimination were perceived to be related to class, race, and language. While discrimination in medical settings was certainly much more subtle than discrimination in general settings, participants' stories, their quotes, and the resultant themes suggest that medical discrimination exists. It was not unusual in our study for participants to deny that they were treated unequally by others, yet proceed to describe breast cancer treatment experiences that were consistent with poor quality of care. These observations led us to believe that single questions asking about unequal treatment are likely to be under-reported because respondents generally have no sense about what treatments they should receive or what quality of care others receive. Our qualitative results suggest that more specific questions about different aspects of the medical encounter are needed to accurately capture the extent of medical discrimination.

- Combining both the results from the qualitative analysis and a comprehensive literature review, we have developed an extensive tool for assessing health care discrimination, with many questions developed de-novo. This tool has been translated into several languages, as described above, and will be cognitive- and pilot-tested.

CONCLUSIONS

Despite continued delays, we have made good progress, the result of which has culminated in the development of a comprehensive survey instrument and drafts of novel manuscripts. Overall, the study has been largely successful thus far, identifying many important themes from the qualitative data analysis and developing a carefully designed survey instrument to be cognitive and pilot tested.

REFERENCES

None.

APPENDICES
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Study Focus Group and Qualitative interview outcomes and response rates by ethnic group and interview type

Interview type / Outcome	Numbers of subjects by race/ethnicity							TOTAL
	White	Chinese	African American	Hispanic	Filipina	Japanese	Other	
Focus group								
Invitation letter sent	50	87	46	52	61	33	n/a	329
Ineligible	7	2	1	14	16	7	n/a	47
Refused	15	29	3	14	31	11	n/a	103
Participated	6	11*	6	5	3	5	n/a	36
Lost to follow up	5	-	-	10	9	1	n/a	25
Not needed**	12	23	7	7	-	8	n/a	57
Not reached***	5	22	29	2	2	1	n/a	61
Response rate, % (of contacted and eligible)	28.6%	27.5%	66.7%	26.3%	8.8%	31.3%	n/a	25.9%
Qualitative (one-on-one) interview								
Invitation letter sent	20	45	18	18	20	19	21	161
Ineligible	2	4	-	5	1	1	7	20
Refused	4	19	1	6	5	11	4	50
Participated	3	6****	3	3	3	3	5+	26
Lost to follow up	1	3	-	1	-	1	1	7
Not needed	10	6	6	3	2	2	-	29
Not reached	-	7	8	-	9	1	4	29
Response rate, % (of contacted and eligible)	42.9%	24.0%	75.0%	33.3%	37.5%	21.4%	55.6%	34.2%

* 2 focus groups; 6 participants in Mandarin focus group and 5 participants in Cantonese focus group.

** Not needed = participants who were contacted but not needed for the focus group or qualitative interview because the goal for number of participants was reached; these women will be re-contacted for subsequent phases of the study.

*** Not reached = participants who had not been reached by the time we reached our goal numbers for the focus group or qualitative interviews, but who are not necessarily lost to follow up or whose addresses still need to be traced.

**** 3 Mandarin; 3 Cantonese

+ 2 Discovered ineligible after interviewing.